Remarks

Claims 1-4, 7-11, 30, 31, 34-36, 42, 43, 49, 55 and 59-73 are pending in the application.

§112 Rejections

I. Claim 1 was rejected under 35 USC §112, 1st paragraph for non-enablement.

Examiner asserts that Applicants failed to provide a definition for prodrug. Applicants would like to point out to the Examiner, page 29, lines 16-22 of specification wherein the term "prodrug" is defined as "a compound that is transformed *in vivo* to yield a compound of Formula (I) or a pharmaceutically acceptable salt, hydrate or solvate of the compound." In addition references and examples of how one would make various prodrugs are described in the specification on page 29, line 16 through - page, 30, line 21. Examiner goes on to assert that no working example of a prodrug of a compound according to the claims is provided. It has never been a requirement to provide working examples of an invention. The references and description provide more than adequate direction for one in the art to make a prodrug which is sufficient for enablement under §112, 1st paragraph.

Although Applicants disagree with Examiner's assertion of non-enablement of prodrugs, Applicants respectfully submit that the amendment of Claim 1 to exclude prodrugs renders the rejection moot. Applicants reserve the right to pursue prodrugs in a subsequently filed continuation application.

II. Claims 60, 64, 65, 69-73 were rejected under 35 USC §112, 1st paragraph, as failing to comply with the written description requirement.

Examiner asserts that the claims contain subject matter that was not described in the specification in such a way to convey reasonably to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. She goes on to quote in italics a listing of terms in non-rejected claims (Claims 61 and 67); however, she did reject Claim 71. This is totally inconsistent. Applicants are not sure what the Examiner is rejecting.

In addition, she only argues against the anti-obesity agents yet she included (1) Claim 64 which is directed to a method of using a composition that contains no additional pharmaceutical agents (i.e., use of the Composition of Claim 55 - compound of Claim 1 + a pharmaceutically acceptable excipient, diluent, or carrier); (2) Claims 60 and 70 which contain agents other than anti-obesity agents (e.g, a

nicotine receptor partial agonist, an opioid antagonist, a dopaminergic agent, an attention deficit disorder agent); and (3) Claims 65, 69, 72 and 73 which are directed to an additional pharmaceutical agent without any explanations for the rejection of this subject matter.

Examiner goes on to assert that "Applicants have disclosed no species and have made no assertion that there is any correlation between the biological function of .....and its structure" Claims 61, 67 and 71 clearly state that the listed agents are anti-obesity agents - "said anti-obesity agent is selected from the group consisting of...." In the specification on page 35, line 15 through page 37, line 6 several species are disclosed as well as references for how to make and use such compounds. In addition, several species are also disclosed as examples of a useful nicotine partial agonist, opioid antagonist, dopaminergic agent, and attention deficit disorder agent (ADD/ADHD agent). See page 37, line 7-22.

Applicants respectfully disagree with Examiner's assertion that the agents listed in the claims are not recognized in the pharmaceutical arts. Each of the agents are well-known to those skilled in the pharmaceutical arts. One need only to enter the terms into Google and one will find a significant number of references in addition to those provided by Applicants in the specification.

Examiner goes on to assert that "the pharmacist of ordinary skill in the art would not know what the listed agents mean. Firstly, a pharmacist is not necessarily one of ordinary skill in the art of drug development. A more appropriate artisan would be a pharmaceutical chemist or physician, both of which would be well trained in the agents listed for a particular receptor or mechanism of action. Second, oftentimes drugs are listed by their mechanism of action; therefore, it is well within the skill of the artisan to determine the identification of useful agents in conjunction with the guidance provided in the specification on pages 35-38. For example, see, Goodman & Gilman's The Pharmacological Basis of Therapeutics, Eds. Hardman, J.G. and L.E. Limbird, McGraw-Hill, which is well-known to those of skill in the art. Therefore, Applicants respectfully submit that the specification provides more than adequate written description to support the claims.

Applicants also note that controlling precedent requires that the US PTO accept the objective truth of Applicants' teachings of enablement unless there is a reason to doubt these teachings. Applicants respectfully submit that there is no reason to doubt the objective truth of the statements contained within the Specification upon which Applicants rely for enabling support.

> As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing the defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for the enabling support. In Re Marzocchi, 439 F.2d 220,222 (CCPA 1971).

The burden is on the Examiner to come forward with *evidence* as to why assertions of utility should not be accepted. In the instant case, the Examiner has merely made conclusory statements without any specific evidence why Applicant's assertions should not be accepted as true. Without such supporting information, the rejection of the specification/claims under 35 USC §112, 1st paragraph for lack of enablement is contrary to well established law.

III. Claims 60, 64, 65, 69-74 were rejected under 35 USC §112, 2nd paragraph as being indefinite.

As discussed above, the Examiner again rejects Claim 71 but not Claims 67 and 71 which is inconsistent. In addition, no argument is given for the subject matter within the remaining claims. Examiner's argument is based solely on the list of anti-obesity agents which are described in more detail in the specification on page 35, line 15 through page 37, line 6 several species are disclosed as well as references for how to make and use such compounds. Applicants also described several different species that serve for examples of a representative nicotine partial agonist, opioid antagonist, dopaminergic agent, and attention deficit disorder agent (ADD/ADHD agent). See page 37, line 7-18.

In addition, a references are provided which provides detailed guidance on how to make and use the various pharmaceutical agents. Those skilled in the art are well aware of when and how to make the different pharmaceutical agents listed to acquire a desired effect which will depend upon the particular purpose for which the drug is to be used. Applicants provide more than ample guidance to direct the reader on how to make the make and use the different pharmaceutical agents through general guidance and the cited references. Those of skill in the art along

with the guidance provided in the specification could easily identify agents useful in the practice of the present invention.

It is well established that an inventor is not required to exemplify every species and/or embodiment of his/her invention. In fact, there is no requirement to provide any working examples. To satisfy the enablement requirement, one must provide sufficient information to enable one of ordinary skill in the art to practice the invention. To include every minute detail in the specification would be superfluous and make it difficult to identify the new or important aspects of the invention. For that reason, Applicants respectfully submit that the general description of pharmaceutical agents and the discussion of the various classes of agents in the specification as well as the cited references provides ample disclosure for one skilled in the art to practice the invention as claimed. Examiner has provided no specific evidence to the contrary.

Applicants would also like to remind the Examiner that the claims are read in light of the specification. Clearly, the specification provides more than ample description of what Applicants mean by the term anti-obesity agent (as well as other pharmaceutical agents) without inclusion of every permutation of the term in the claims which would make the claims very lengthy and difficult to read. Therefore, Applicants respectfully submit that the term "pharmaceutical agent" and in particular "anti-obesity agent, nicotine partial agonist, opioid antagonist, dopaminergic agent, and attention deficit disorder agent (ADD/ADHD agent)" as used in the current application are not indefinite.

Respectfully Submitted:

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